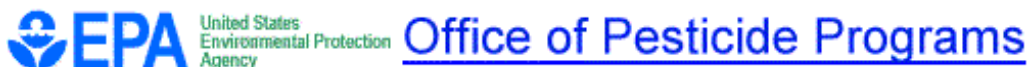


**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

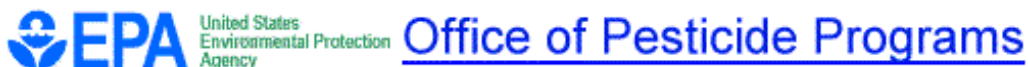


Antimicrobials Division (AD)

3/23/2017

EPA Reg#: 63761-8		DP Barcode: 434637	
		Submission #: 981060	E-Sub#:
Product name: Sterilex Ultra Disinfectant Cleaner Solution 1		Registrant: Sterilex Corporation	
Reviewer's name: Narayanan Parthasarathy		AD/PSB/CTT- Product Chemistry Review	
Agency due date:		PSB received date: 7/12/2016	
CTT received date:		Science received date: 7/12/2016	
Formulation type: EP		Pesticide classification: Antimicrobial	
Integrated system: <input type="checkbox"/>	Nonintegrated system: <input checked="" type="checkbox"/>	Food use: <input type="checkbox"/>	Nonfood use: <input checked="" type="checkbox"/>
Action Code: 676		Date Completed: 3/23/2017	
PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
069154	85409-23-0	n-Alkyl (C ₁₂ 68%, C ₁₄ 32%) dimethyl ethylbenzyl ammonium chloride	3.00%
069104	68391-01-5	n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%) dimethyl benzyl ammonium chloride	3.00%
000595	7722-84-1	Hydrogen Peroxide	6.30%
Molecular Structure (Optional)			
MRID(s): To be assigned			
Approver: Karen P. Hicks		Approved date:	
Guideline: Product Chemistry Group B 830.6317, 830.6320 & 830.7000 Guidelines			
Comments: Response in support of PDCI 069104-30932 for reregistration case 0350 ADBAC			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Antimicrobials Division (AD)

3/23/2017

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # **63761-8**
Product Name: **Sterilex Ultra Disinfectant Cleaner Solution 1**
DP Barcode: **434637**

From: Narayanan Parthasarathy, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

A handwritten signature in black ink, appearing to read "N. Parthasarathy", is written over a horizontal line.

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

A handwritten signature in black ink, appearing to read "K. Hicks", is written over a horizontal line.

To: Jose Gayoso/ Timothy Young
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Sterilex Corporation

Action code: 676

Formulation from Label

<u>Active Ingredients</u>	% by wt.
n-Alkyl (C ₁₂ 68%, C ₁₄ 32%) dimethyl ethylbenzyl ammonium chloride	3.00%
n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%) dimethyl benzyl ammonium chloride	3.00%
Hydrogen Peroxide	6.30%

BACKGROUND: The registrant, Sterilex **Corporation** is submitting Product Data Call-In response 069104-30932 for the product, **Sterilex Ultra Disinfectant Cleaner Solution 1, EPA Reg # 63761-8**. This antimicrobial, end-use, non-integrated, non-food use product is formulated as a disinfectant.

Supporting Documents:

- 1) Cover Letter (7/1/2016).
- 2) Previously approved Basic CSF (10/22/2015).
- 3) MRID #To be assigned-Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Storage Stability, Corrosion Characteristics and pH (830.6317, 830.6320 & 830.7000 Guidelines).
- 4) Data Matrix (7/1/2016).

FINDINGS:

1. 830.6317: Storage Stability: The tests were conducted with one lot of the test substance stored in its commercial packaging materials, high density polyethylene (HDPE) at room temperature at initial, and after 3,6,9 and 12 months. The Active Ingredients (AIs), namely, hydrogen peroxide and quaternary amine concentrations were determined.

% Quaternary Amines & % Hydrogen Peroxide. No physical changes were noted at the afore-mentioned time intervals.

Interval	% Quaternary Amines*	% Hydrogen Peroxide*
Initial	6.07	6.39
After 3 months at Room Temperature	6.07	6.34
After 6 months at Room Temperature	6.07	6.31
After 9 months at Room Temperature	6.12	6.17
After 12 months at Room Temperature	6.04	6.15

*- Average of duplicate analysis

% Quaternary Amines: Nominal Concentration, 6.00%. Upper Certified Limit, 6.30%. Lower Certified Limit, 5.70%.

% Hydrogen Peroxide: Nominal Concentration, 6.30%. Upper Certified Limit, 6.62%. Lower Certified Limit, 5.99%.

2. 830.6320: Corrosion Characteristics: No corrosion characteristics were noted on the commercial packaging material, HDPE, during storage at room temperature for 1 year.
3. 830.6320: pH, 1% solution: pH was determined to be 5.20, 5.09, 4.99, 4.55, 4.60 at initial, after 3, 6, 9 and 12 months' intervals respectively.

CONCLUSIONS:

Basic CSF (10/22/2105) had been previously approved. The registrant had provided Storage Stability (830.6317), Corrosion Characteristics (830.6320) and pH (830.7000) for product, **Sterilex Ultra Disinfectant Cleaner Solution 1, EPA Reg # 63761-8**. The registrant satisfied the sixteen-month response to PDCI069104-30932 for the reregistration of the above product.